K021179

JUL 5 2002

SMDA 510(k) SUMMARY

A. Submitter's Name, Address, Phone and Fax Numbers

1. Submitter's Name

Name & Address of manufacturer:	Olympus Optical Co., Ltd. 2-3-1 Shinjyuku Monolis Nishi-Shinjuku, Shinjyuku-ku Tokyo, 163-0914□Japan
Registration No.:	8010047
Address, Phone and Fax Numbers: of R&D Department, Endoscope Division	2951 Ishikawa-Cho, Hachioji-shi, Tokyo 192-8507 Japan TEL 81- 426-42-5177 FAX 81-426-46-5613

2. Manufacturer site/Sterilization site

Name & Address of manufacturer:	Ashitaka Factory of Terumo Corporation 150, Mainmaigi-cho, Fujinomiya-City Shizuoka, 418-0015, Japan
Registration No.□	9681834

B. Name of Contact Person

Name:	Ms. Laura Storms-Tyler
Address, Phone and Fax Numbers:	Olympus America Inc. Two Corporate Center Drive Melville, New York 11747-3157 TEL: (631) 844-5688 FAX: (631) 844-5416

C. Device Name, Common Name, Classification Name and Predicate Devices

Trade Name:	Disposable Guidwire G-205-3545S, G205-3545A
Common Name:	Guidewire
Classification:	Endoscope and accessories 21 CFR 876.1500
Predicate Device:	Guide Wire G35-2LB (Olympus Optical Co.,Ltd.) #K933110
	Climber (Terumo) #K971937
	Lagwire 5658-1/5659-1 (Boston Scientific) #K922302

D. Description of the Device(s)

G-201-35-45, G-202-35-45 are resin-treated coated gidwire. Removal of the guidewire is not necessary during sphinctecterotomy . G-201-35-45 is straight distal portion type, G-202-35-45 is angle distal portion type. These instruments have been designed to be used with Olympus Endo-Therapy Accessories. which are applicable for φ0.89mm (0.035 inch) diameter guidewires. These instruments are equipped with Laser-markers at the distal portion to conform guidewire placement under fluoroscopy endoscopic maneuvering.

E. Intended Use of the Device(s)

This instrument has been designed to be use with Olympus Endo-therapy Accessories.

The instrument is used as guidwire of endoscopic accessories for biliary duct, including not only common bile but cystic, pancreatic, right and left hepatic ducts

F. Summary including Conclusions drawn from Non-clinical Tests

When compared to the predicate device, Disposable Guidewire G-205-3545S, G-205-3545A does not incorporate any significant changes in the intended use, method of operation, material, or design that could affect the safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 5 2002

Olympus Optical Co., Ltd.
c/o Ms. Laura Storms-Tyler
Director, Regulatory Affairs
Olympus America, Inc.
Two Corporate Center Drive
MELVILLE NY 11747-3157

Re: K021179
Trade/Device Name: Olympus Disposable Guidewire, Models G-205-3545S and G-205-3545A
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: 78 KOG
Dated: April 11, 2002
Received: April 15, 2002

Dear Ms. Storms-Tyler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K021179

Device Name:
Disposable Guidewire G-205-3545S, G-205-3545A

Indications for Use:

This instrument has been designed to be use with Olympus Endo-therapy Accessories. The instrument is used as guidwire of endoscopic accessories for biliary duct, including not only common bile but cystic, pancreatic, right and left hepatic ducts

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR _____ Over-The-Counter Use
(Per 21 CFR 801.109)

Nancy C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K021179

(Optional Format 1-2-96)